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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,853	01/05/2001	Brian M. Hauge	16517.187	4137

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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/754,853

Applicant(s)

HAUGE ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 78-106 is/are pending in the application.
- 4a) Of the above claim(s) 99-106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 78-98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/08/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 8 November 2004 has been entered.

Status Of The Application

2. This Office action is in response to the Amendment and Remarks filed 8 November 2004.
3. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments to the claims or in view of Applicant's remarks.
4. The rejection under 35 USC § 112, first paragraph, for New Matter is withdrawn in view of Applicant's amendments and response as directed to Table 4, for example, in the specification.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

6. Newly submitted claims 99-106 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 99-104 are directed to a new invention, that being a method for selecting a soybean plant

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having an rhg1 SCN resistant allele using a nucleic acid marker, classified in class 435, subclass 6, for example. Claims 105 and 106 are directed to the same invention as Group II, original claims 11-18, which was not elected with traverse in the Response filed 7 October 2002.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 99-106 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR § 1.142(b) and MPEP § 821.03.

Information Disclosure Statement

7. The information disclosure statement filed 8 November 2004 has been considered, a signed copy is attached hereto.

Claim Rejections - 35 USC § 112

8. Claim 78 remains rejected and new claim 91 is rejected as being indefinite because the sole designation of a plant by its breeding line name or number, or by a commercial variety designation such as 'A2869' and 'AG4301' Asgrow Seeds (see page 48, 1st paragraph of the specification), is arbitrary and creates ambiguity in the claims. For example, the plants disclosed in this application could be designated by some other arbitrary means, or the assignment of the breeding line name could be arbitrarily changed to designate another plant. If either event occurs, one's ability to determine the metes and bounds of the claim would be impaired. See *In re Hammack*, 427 F.2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970). This rejection is repeated for the

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reason of record as set forth in the last Office action mailed 8 June 2004. Applicant's arguments filed 8 November 2004 have been fully considered but they are not persuasive. Applicants argue that plant breeding line names or commercial variety designations provide an unambiguous reference to individual plants, for example, soybean plants are listed according to plant breeding line name in the Germplasm Resources Information Network (GRIN) Database, which is maintained by the National Plant Germplasm System of the Agricultural Research Service, of the United States Department of Agriculture, see, e.g., http://www.ars-grin.gov/cgi-bin/npgs/html/tax_site_acc.pl?SOY%20Glycine%20max. This argument is not found to be persuasive for the reasons of record. The soybean plant 'A2869' or 'AG4301' could be designated by another arbitrary name by Asgrow Seed Company. In addition, GRIN states that soybean lines PI200499 and PI407922 are susceptible to Race 3 SCN, and thus would not comprise an rhg1 SCN resistant allele. It is unclear if Applicant is referring to different soybean lines or to those publicly disclosed in GRIN.

Claim 86 is indefinite because the limitation "screening" at line 2 is referring to "nucleic acid markers" at line 3, because it is unclear how one of skill in the art introgresses an allele by screening markers, the metes and bounds of the claim are unclear.

Claims 79-90 and 92-98 are also indefinite because they do not obviate the indefiniteness of either Claim 78, 86 or 91, from which they are dependent.

9. Claims 78-90 remain rejected and claims 91-98 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The

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claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 8 June 2004. Applicant's arguments filed 8 November 2004 have been fully considered but they are not persuasive.

Applicants argue that the polymorphisms listed in Table 2 provide a recitation of a representative number of members of the genus of polymorphisms set forth in the claims, as such, when considered in combination with the complete nucleotide sequence of SEQ ID NO: 2 and the description of rhg1 in the specification, the polymorphisms listed in Table 2 reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed genus of polymorphisms. Applicants argue that the instant specification also complies with the written description requirement with respect to the genus of nucleic acid markers required to identify an rhg1 SCN resistant allele, Applicants submit that Table 1, in combination with the sequence listing, describes a representative number of nucleic acid primer sequences that may be used to detect and analyze the polymorphisms set forth in Table 2 (pages 15 and 16 of the Remarks). These argument are not found to be persuasive because said claims are directed to any nucleic acid marker to identify an rhg1 SCN resistant allele, wherein Applicant has only described single nucleotide polymorphisms (SNPs) and insertion/deletion sites (INDEL) relative to a reference soybean line, i.e. reference line 'A3244' in Table 2 of the specification (on page 44).

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Because Applicant only describes SNPs and INDEL mutations relative to a single reference soybean line, it is unclear that Applicant has adequately described nucleic acid markers to identify an rhg1 SCN resistant allele in progeny soybean plants as broadly claimed. The evidence in Table 1 of the specification does not describe the structure of the primers, only their names (see page 17 of the specification).

The claims lack adequately written description because soybean plants designated 'PI200499' and 'PI407922' do not appear to comprise an rhg1 SCN resistant allele, and Applicant does not describe SCN resistant progeny thereof (see rejection under 35 USC 112, second paragraph above). Applicant states in the specification that progeny encompass plants that have 12.5% or less genetic material derived from one of the two original crossed plants (page 64, 2nd paragraph of the specification). It is clear from the specification that Applicant had not described such progeny as broadly claimed.

Because the instant claims are directed to the use of SCN resistant progeny, and there is no indication that the SCN resistant allele is inherited from the recited specific soybean plants, Applicant has failed to adequately describe the genus of SCN resistant soybean plants required to practice the invention as broadly claimed.

10. Claims 78-90 remain rejected and claims 91-98 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason

of record as set forth in the last Office action mailed 8 June 2004. Applicant's arguments filed 8 November 2004 have been fully considered but they are not persuasive.

Applicants note that one of skill in the art would understand that Table 2 depicts the nucleotide base identity at thirty exemplary single nucleotide polymorphism ("SNP") positions in fifteen exemplary soybean lines (page 17 of the Remarks). Applicants argue that the specification describes the relative SCN resistance characteristics of various soybean lines and that the specification sets forth methods for extracting DNA from soybean plants, for identifying and detecting SNPs, and for detecting other types of polymorphisms. Applicants argue that the information in the specification could be used to identify additional primers and additional SNPs that would be informative in screening for SCN resistance, and that the performance of routine and well-known steps cannot create undue experimentation even if it is laborious (page 18 of the Remarks). Applicants argue that there is no legal requirement that each and every polymorphism encompassed by the claims be useful for every contemplated utility. What is required is that the art worker knows how to determine, after reasonable experimentation, whether a particular polymorphism is useful for a particular utility (page 19 of the Remarks).

These arguments are not found to be persuasive. Applicant's example in the paragraph spanning pages 17-18 of the Remarks do not persuade because both the reference line 'A3244', and resistant line 'Peking' have a G at SNP position 45173, relative to SEQ ID NO: 2, even though susceptible line 'Noir' has an A at said position. It is unclear from the teachings of Table 2 of the specification what SNPs or

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combinations thereof identify a SCN resistant progeny plant comprising an rhg1 SCN resistant allele. It is the Examiner's opinion that Applicant invites undue trial and error experimentation by one of skill in the art to use other reference soybean lines other than 'A3244' as exemplified in Table 2 and/or to identify a myriad of other SNPs to determine how to use the method(s) as broadly claimed. The art teaches that chromosomal segment duplication in the soybean genome reduces the efficiency of SNP discovery and that the actual probability of identifying at least one SNP in a 574-bp fragment, for example, is lower than predicted statistically (Zhu *et al* 2003, Genetics 163:1123-1134, see pages 1132-1133). The art teaches that insertion/deletion mutations (INDELs) are difficult to detect in heterozygous individuals and that haplotypes cannot be unambiguously determined except by cloning the PCR products to isolate individual haplotypes (Rafalski 2002, Plant Science 162: 329-333, see page 330, left column). Hence, given the limited guidance by Applicant, the nature of the invention, the unpredictability of the art and the breadth of the claims, it would have required undue trial and error experimentation by one of skill in the art to use the invention as broadly claimed.

11. Claims 78-85 remain rejected and claims 91-98 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 8 June 2004. Applicant's

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arguments filed 8 November 2004 have been fully considered but they are not persuasive.

Applicants disagree that the claimed invention employs novel plants, that the GRIN Database, maintained by the National Plant Germplasm System of the Agricultural Research Service, of the United States Department of Agriculture, available teaches public availability of the PIXXXXXX lines. Applicant argues that with respect to soybean lines 'A2869' and 'AG4301' Applicants respectfully submit that Asgrow Seeds are now sold through the assignee of the instant application (page 20 of the Remarks). Applicant argues that the soybean plants required to practice the claimed invention are known and readily available. These arguments are not found to be persuasive. GRIN states that soybean lines PI200499 and PI407922 are susceptible to Race 3 SCN, and thus such publicly available soybean lines would not comprise an rhg1 SCN resistant allele. An attempt to locate soybean line 'AG4301' on the Monsanto web site was unsuccessful, the web site saying there was not a line 'AG4301' available. Because 'A2869' and 'AG4301' soybean lines are not "publicly" available without restriction, Applicant must make an enabling deposit of said lines to enable the claimed invention.

Claim Rejections - 35 USC § 102/103

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 78 and 79 are rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Lightfoot *et al* (US Patent 6,300,541 B1, filed 14 January 1997).

Lightfoot discloses a method of conveying soybean sudden death resistance into non-resistant soybean germplasm comprising using marker SATT309 to identify a resistant soybean and introgressing said resistance into a non-resistant soybean germplasm (claim 4). Lightfoot discloses that said source of resistance can be from a descendant of Forrest (claim 6). The Examiner notes that the *rhg1* SCN resistant allele in Forrest and in PI548988 of the instant invention is inherited from soybean line Peking. Given that Applicant defines "progeny thereof" as any descendent, a *rhg1* SCN resistant descendant of Forrest and a *rhg1* SCN resistant descendant of PI548988 would be indistinguishable one from the other. Lightfoot also discloses that marker SATT309 segregates with *rhg1* SCN resistance (Figure 23). Because one of skill in the art would be using a descendant of Forrest and selecting using marker SATT309 prior to ingressing into a non-resistant soybean, one of skill in the art would in fact be practicing the method in the order recited by Applicant, and selecting members of a segregating population having an *rhg1* SCN resistant allele. Soybean line Forrest has yellow

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soybeans. See *Integra LifeSciences I Ltd. V. Merck KGaA* 50 USPQ2d 1846, 1850 (DC SCalif 1999), which teaches that where the prior art teaches all of the required steps to practice the claimed method and no additional manipulation is required to produce the claimed result, then the prior art anticipates the claimed method.

The teachings of Lightfoot *et al* can be found in the previous Office action.

Lightfoot does not specifically teach a method of using rhg1 SCN resistant progeny of PI548988.

Given that rhg1 SCN resistant progeny of Forrest and PI548988 would be indistinguishable, the claims would have been obvious to one of ordinary skill in the art at the time of Applicant's invention because Forrest and PI548988 comprise the same rhg1 SCN resistant allele. One of ordinary skill in the art at the time of Applicant's invention would have been motivated to use other soybean plants comprising an rhg1 SCN resistant allele inherited from Peking, and would have had a reasonable expectation of success given the teachings of Lightfoot *et al*.

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Conclusion

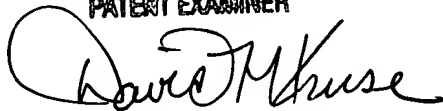
15. No claims are allowed.
16. Claims 80-98 appear free of the prior art.
17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

DAVID H. KRUSE, PH.D.
PATENT EXAMINER

David H. Kruse, Ph.D.
3 February 2005



18. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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